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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,938	08/31/2001	David M. Mann	CI-0004	8959

7590 12/17/2002  
FLESHNER & KIM, LLP  
P.O. Box 221200  
Chantilly, VA 20153-1200

EXAMINER
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WINSTON, RANDALL O

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 12/17/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/942,938

Applicant(s)  
Mann et al.

Examiner  
Randall Winston

Art Unit  
1654



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-85 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-85 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some\* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

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## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to a method for sterilizing preparation of one or more digestive enzymes that is sensitive to radiation, said method comprising irradiating said preparation of one or more digestive enzymes with radiation, classified in class 435, subclass 173.1, for example.

II. Claim 2, drawn to a method for sterilizing preparation of one or more digestive enzymes that is sensitive to radiation, said method comprising adding to said preparation of one or more digestive enzymes at least one stabilizer, classified in class 424, subclass 94.3, for example.

III. Claim 3, drawn to a method for sterilizing preparation of one or more digestive enzymes that is sensitive to radiation, said method comprising reducing the residual solvent content of said preparation of one or more digestive enzymes, classified in class 435, subclass 173.1, for example.

IV. Claim 4, drawn to a method for sterilizing a preparation of one or more digestive enzymes that is sensitive to radiation, said method comprising reducing the temperature of said preparation or one or more digestive enzymes, classified in class 435, subclass 173.2, for example.

V. Claim 5, drawn to a method for sterilizing a preparation of one or more digestive enzymes that is sensitive to radiation, said method comprising applying to said preparation of one

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or more digestive enzymes at least one stabilizing process, classified in class 435, subclass 94.3, for example.

VI. Claims 6-58, drawn to a method for sterilizing a preparation of one or more digestive enzymes that is sensitive to radiation, said method comprising applying to said preparation of one or more digestive enzymes at least two stabilizing processes, classified in class 435, subclass 94.3, for example.

VII. Claim 59, drawn to a composition comprising at least one preparation of one or more digestive enzymes and at least one stabilizer, classified in class 435, subclass 183, for example.

VIII. Claims 60-85, drawn to a composition comprising at least one preparation of one or more digestive enzymes, wherein the residual solvent content of said preparation of one or more digestive enzymes, classified in class 435, subclass 188, for example.

2. The inventive groups above are directed to different inventions which are not connected in design, operation, and/or effect. These methods (Inventions I-VI and IX, methods for sterilizing a preparation of one or more digestive enzymes that is sensitive to radiation, are distinguishable, each from the other, by each of applicants' methods has a different mode of operation, i.e., applicants said method comprising of is different for each method as examiner has indicated by the underlined words above) and a composition is distinct since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. In addition, one would not have to practice the

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various methods and/or use applicants compositions at the same time to practice just one method alone and/or one composition alone.

3. The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all the above inventions in one application.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirements be traversed (37 CFR 1.143).

Any inquiry concerning this communication should be directed to Randall Winston at telephone number (703) 305-0404. The examiner can normally be reached during the hours of 08:30 to 17:00 Eastern.

If attempts to reach the examiner by telephone are unsuccessful. A message may be left on the voice mail. The fax number the Art 1654 is (703) 308-4242 or 305-3014. Any inquiry of a general nature or relating to the status of this application should be directed to the Group

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receptionist whose telephone number is (703) 308-0196. My supervisor, Brenda Brumback, may be contacted at (703) 306-3220.

Randall O. Winston  
Examiner, 1651

A handwritten signature in black ink, appearing to read 'CHRISTOPHER R. TATE', with a stylized flourish at the end.

CHRISTOPHER R. TATE  
PRIMARY EXAMINER